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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/506,877 | 07/29/2005 | Steven P. Gyi | 56954 (70207) | 3582 |
| 21874 | 7590 | 10/03/2007 | | |
| EDWARDS ANGELL PALMER & DODGE LLP | | | EXAMINER | |
| P.O. BOX 55874 | | | FOSTER, CHRISTINE E | |
| BOSTON, MA 02205 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,877

Applicant(s)

GYGI ET AL.

Examiner

Christine Foster

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-26 and 28-29, drawn to a method for determining a site of ubiquitination by determining the presence of an isopeptide bond.

Group II, claim(s) 1-6, 11-13, and 19-29, drawn to a method for determining a site of ubiquitination by determining a mass difference between a test peptide and a reference peptide.

Group III, claim(s) 30, drawn to a computer memory.

Group IV, claim(s) 31, drawn to a kit comprising a ubiquitin binding molecule.

Group V, claim(s) 32-37, drawn to kits comprising an antibody that specifically recognizes a peptide product.

Group VI, claim(s) 38-41, drawn to methods of detecting a site and/or amount of ubiquitination in a ubiquitin molecule.

Group VII, claim(s) 42-43, drawn to an antibody specific for a modified form of a ubiquitin molecule.

Group VIII, claim(s) 44, drawn to a composition comprising a peptide internal standard.

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2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VIII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. It is noted that the claims encompass divergent subject matter from a number of different statutory classes of invention. The technical feature linking the inventions listed above appears to be that of ubiquitinated polypeptides, which does not represent a special technical feature since ubiquitination of proteins was well known in the art.

Furthermore, the technical feature of Group above appears to be that of obtaining a plurality of ubiquitinated polypeptides; digesting the polypeptides with a protease to generate peptides, and identifying a site of ubiquitination by determining an isopeptide bond in a digested peptide by mass spectrometry.

Wang et al. ("Antibacterial peptides in stimulated human granulocytes Characterization of ubiquitinated histone H1A" Eur J Biochem. 2002 Jan;269(2):512-8) teach obtaining a plurality of proteins from stimulated granulocytes by HPLC purification; digesting the proteins with a protease (trypsin) to generate peptides, and identifying a site of ubiquitination by mass spectrometry (see in particular the abstract; pages 513-514, the sections "Extraction and purification of proteins..."; "Protein analysis"; and "Mass spectrometry"). In particular, Wang et al. teach that tandem mass spectra of H1A fragments indicated the presence of a covalent bond between the side chain of the C-terminal Lys222 of H1A and ubiquitin (which is an isopeptide

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bond as recited in claim 1). See pages 514-515, the section "Purification and identification..." and especially the paragraph bridging pages 514-515; and page 517, left column). As such, Wang et al. teach obtaining a plurality of ubiquitinated polypeptides; digesting the polypeptides with a protease to generate peptides, and identifying a site of ubiquitination by determining an isopeptide bond in a digested peptide by mass spectrometry.

Therefore, the technical feature linking the inventions does not constitute a special technical feature as it does not represent a contribution over the prior art.

In addition, Groups I-VIII each have technical features that are unrelated to the other groups. Group I includes the step of determining the presence of an isopeptide bond by mass spectrometry, which is not a limitation of the other Groups; Group II includes the step of identifying a mass difference between a test peptide and a reference peptide comprising a known identical amino acid sequence as the test peptide; Group III is a computer memory comprising data files; Group IV is a kit comprising a light-absorbent matrix; Group V is a kit comprising an antibody that specifically recognizes a peptide product; Group VI is a method of detecting a ubiquitin remnant in a peptide comprising a lysine residue at positions 6, 11, 27, 29, 33, 48, and 63; Group VII is an antibody specific for a modified form of ubiquitin; and Group VIII is a composition comprising a peptide internal standard.

Accordingly, Groups I-VIII are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

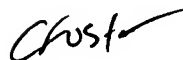
Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641



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